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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,595	09/25/2003	Richard Jean-Pierre	1076-002US01	7492

7590

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EXAMINER
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COLLINS, MICHAEL

ART UNIT	PAPER NUMBER
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3651

DATE MAILED: 08/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary****Application No.**

10/670,595

**Applicant(s)**

JEAN-PIERRE, RICHARD

**Examiner**

Michael K. Collins

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 and 22-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 22-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/22/03, 10/18/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Species I-II in the reply filed on 06/19/2006 is acknowledged. The traversal is on the grounds that the search required for one species would be required for the others because they include similar limitations. This argument is persuasive, and therefore the election of species has been withdrawn. Claims 1-20 and 22-32 have been examined in this action.

### ***Claim Objections***

2. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 22-32 been renumbered 21-31.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 4 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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- Regarding claim 4, the applicant claims, “wherein the wireless communication is via infrared light emitting diode”. Wireless communication is not mentioned in any previous claims.
- Regarding claim 16, the applicant claims, “a second indicator for indicating when the user should take the dose of medication”. Where is the first indicator?

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1,2, and 5-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Schollmeyer et al. (USP 4,504,153).

Regarding claim 1, Schollmeyer et al. disclose a medication compliance device comprising:

- a base station (9) having a communication link (8) and memory, the base station for receiving and storing medication-taking data and compliance data
- a portable cap assembly for association with a container of medication, the portable cap assembly comprising:
  - a communication link (see column 3 lines 24-26)
  - a memory (see column 4 lines 28-38)
  - an indicator (see column 4 lines 59-61)

- a sensor (see column 3 lines 34-36)
- a controller (16) for directing the communication link to receive and transmit and the memory to store the medication-taking data, for directing the indicator to activate according to the medication-taking data, for directing the sensor to gather and the memory to store the compliance data, and for directing the communication link to transmit the compliance data

Regarding claim 2, Schollmeyer et al. disclose the device of claim 1 wherein the medication-taking data further comprises a medication-taking regimen (see column 1 lines 6-7).

Regarding claim 5, Schollmeyer et al. disclose the device of claim 1 wherein the base station transmits the compliance data to a remote location through a data network (see column 4 lines 55-58).

Regarding claim 6, Schollmeyer et al. disclose the device of claim 1 and further comprising:

- a programming station (5) for programming the portable cap assembly with the medication-taking data
- wherein the portable cap assembly further comprises:
  - a cap (4)
  - a collar (4A) for attaching the cap to a container and interfacing with the programming station

Regarding claim 7, Schollmeyer et al. disclose the device of claim 6 wherein the collar further comprises a pivoting base for dispensing medication from the container (see column 3 line 29).

Regarding claim 8, Schollmeyer et al. disclose the device of claim 1 wherein the indicator is a visual indicator (11).

Regarding claim 9, Schollmeyer et al. disclose the device of claim 1 wherein the indicator is an audible indicator (13).

Regarding claim 10, Schollmeyer et al disclose the device of claim 1 wherein the indicator is a tactile indicator (14).

7. Claims 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Varis (USP 6,702,146).

Regarding claim 17, Varis discloses a medication compliance system comprising:

- a portable medication dispenser (35) having an indicator for inducing compliance with medication-taking data (see column 4 lines 59-61), and a sensor for obtaining compliance data (see column 3 lines 34-40)
- a base station (62) in communication with the dispenser, the base station for transmitting the compliance data from the sensor
- a first computer (64a) in communication with the base station, the first computer for receiving the compliance data
- a programming station (36) in communication with a second computer (66), the programming station for interfacing with the dispenser (35) to program the dispenser with the medication-taking data

Regarding claim 18, Varis discloses the system of claim 17 wherein the base station and first computer communicate through a data network (see Figure 7).

Regarding claim 19, Varis discloses the system of claim 18 wherein the data network is coupled to a data server (64) for storing data for the system.

Regarding claim 20, Varis discloses the system of claim 17 wherein the second computer (66) transmits the medication-taking data to the base station (62), which transmits the medication-taking data to the dispenser (see column 7 lines 26-31).

### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schollmeyer et al. (USP 4,504,153) in view of Weisman (USP 6,302,295).

Regarding claim 3, Schollmeyer et al. disclose the device of claim 2 wherein the portable cap assembly further comprises a top with a child-proof lock mechanism (see column 3 line 29). They do not disclose the top to be transparent. Weisman discloses a transparent top. Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the applicant's invention to modify Schollmeyer et al. by including a transparent top, as disclosed by Weisman, for the purpose of enabling the user to visually determine whether the daily dosage of medication has been taken.

11. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schollmeyer et al. (USP 4,504,153) in view of Weisman (USP 6,302,295) and further in view of Sagar (USP 6,604,650).

Regarding claim 4, Schollmeyer et al. in view of Weisman and in further view of Sagar disclose the device of claim 3. Schollmeyer et al. further disclose a device with a light emitting diode (22). However, they do not disclose a device wherein wireless communication is via infrared light. Sagar discloses wireless communication via infrared light. Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the applicant's invention to modify Schollmeyer et al., as disclosed by Sagar, for the purpose of providing information relevant to the patient's prescription (see column 4 lines 12-13).

12. Claims 11-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schollmeyer et al. in view of Sagar (6,604,650).

Regarding claim 11, Schollmeyer et al. disclose a medication compliance device comprising:



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- a portable cap assembly for attaching to a container, the cap assembly having memory for storing medication-taking data and compliance data (see column 2 lines 19-24), a first indicator for indicating when a user should take a dose of medication stored in the container, and a sensor for sensing that the user has taken the dose of medication
- a programming station (5) for programming the portable cap assembly with the medication-taking data
- a base station (9) having memory for storing the medication-taking data and the compliance data, and wired communication (8) for transmitting the compliance data to a remote location

They do not, however, disclose a cap with wireless communication for transmitting the medication-taking data and compliance data or a base station with wireless communication for receiving the medication-taking data and the compliance data from the portable cap assembly. Sagar discloses wireless communication for transmitting and receiving data between a bottle-cap and a base (see Figure 3). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the applicant's invention to modify Schollmeyer et al. by including wireless communication for the purpose of transmitting and receiving data related to medication taking and compliance, as disclosed by Sagar, for the purpose of providing information relevant to a patient's prescription.

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Regarding claim 12, Schollmeyer et al. in view of Sagar disclose the device of claim 11. Schollmeyer further discloses a device wherein the portable cap assembly further comprises:

- a collar (4A) removably connected adjacent an opening of the container (3)
- a cap removably attached to the collar (see Figure 1 and column 3 lines 30-33)
- wherein the collar and container are disposable and the cap is reusable

Regarding claim 13, Schollmeyer et al. in view of Sagar disclose the device of claim 12 wherein the portable cap assembly further comprises:

- a pivoting base that moves relative to a stationary base of the collar for dispensing the medication from the container (see column 5 lines 60-68)
- wherein the sensor senses cap movement, which is stored as compliance data (see column 4 lines 34-40)

Regarding claim 14, Schollmeyer et al. disclose the device of claim 11 wherein the base station is programmed with medication-taking data from a remote location (see column 4 lines 53-58).

Regarding claim 15, Schollmeyer et al. in view of Sagar disclose the device of claim 11 and further comprising:

- a computer (9) terminal electrically coupled (8) to the programming station (5) for programming the portable cap assembly with the medication-taking data.

Regarding claim 16, Schollmeyer et al. in view of Sagar disclose the device of claim 11 wherein the base station further comprises:

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- a second indicator for indicating when the user should take the dose of medication (see column 4 lines 59-61)
- wherein the second indicator is activated when the cap is within a range for communication with the base station

13. Claims 22-23, and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schollmeyer et al. (USP 4,504,153) in view of Burg II et al. (USP 6,771,165).

Regarding claim 22, Schollmeyer et al. disclose a medication compliance device comprising:

- a collar (4A) for attaching adjacent an opening of a medication container (3),
- a cap (4) attached to the collar, the cap further comprising:
  - a first communication link (17)
  - an indicator for inducing compliance with the medication-taking data (see column 4 lines 59-61)
  - a sensor for sensing compliance with the medication-taking data (see column 3 lines 34-40)
  - a microcontroller (16), activating the indicator according to the medication-taking data, and gathering the compliance data from the sensor

However, he does not disclose the collar having a first communication link and memory for storing medication-taking data and compliance data or the microcontroller to be used for engaging communication with the collar through the communication link. Burg II et al. disclose a collar having a first communication link and memory for storing

medication-taking data and compliance data and a microcontroller to be used for engaging communication with the collar through a communication link. Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the applicant's invention to modify Schollmeyer et al. by including a collar having a first communication link and memory for storing medication-taking data and compliance data and a microcontroller to be used for engaging communication with the collar through a communication link, as disclosed by Burg et al., for the purpose of containing these components and enabling the collar to be free to rotate (see column 9 lines 25-25).

Regarding claim 23, Schollmeyer et al. in view of Burg II et al. disclose the device of claim 22 wherein the cap further comprises:

- a second communication link (26) for transmitting the medication-taking data and compliance data such that the data is accessible through a data network

Regarding claim 25, Schollmeyer et al. in view of Burg II et al. disclose the device of claim 22 wherein the indicator is a visual indicator (11).

Regarding claim 26, Schollmeyer et al. in view of Burg II et al. disclose the device of claim 22 wherein the indicator is an audio indicator (13).

Regarding claim 27, Schollmeyer et al. in view of Burg II et al. disclose the device of claim 22 wherein the collar further comprises:

- a stationary base adjacent the opening of the container (4A)
- a pivoting base coupled to the stationary base (28)
- wherein the pivoting base pivots relative to the stationary base to dispense the medication and the sensor senses movement of the pivoting base

14. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schollmeyer et al. (USP 4,504,153) in view of Burg II et al. (USP 6,771,165) and in further view of Varis (USP 6,702,146).

Regarding claim 24, Schollmeyer et al. in view of Burg II et al. disclose the device of claim 22. However, they do not disclose wherein the collar further comprises a second communication link for receiving the medication-taking data. Varis discloses a collar with a second communication link for receiving the medication-taking data. Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the applicant's invention to modify Schollmeyer et al. by including a collar with a second communication link for receiving the medication-taking data, as disclosed by Varis, for the purpose of transmitting information regarding dispensing events (see column 6 line 45).

15. Claims 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over de la Huerga in view of Sagar (USP 6,604,650).

Regarding claim 28, de la Huerga (USP 6,032,155) discloses a method of inducing and tracking compliance with a medication-taking regimen, the method comprising:

- receiving medication-taking data (see column 2 lines 36-55)
- alerting a user to take a dose of medication (18)
- gathering compliance data (36)
- transmitting the compliance data to a base station (see abstract)

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However, he does not disclose the transmission to specifically be by wireless communication. Sagar discloses transmission by wireless communication. Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the applicant's invention to modify de la Huerga by including wireless communication for the purpose of providing information relevant to a patient's prescription (see column 4 lines 12-13).

Regarding claim 29, de la Huerga in view of Sagar disclose a method further comprising:

- transmitting the compliance data from the base station to a data network (see abstract and 240)
- accessing the compliance data from the network (see column 17 lines 27-34)

Regarding claim 30, de la Huerga in view of Sagar disclose a method wherein medication-taking data is received and compliance data is gathered for a plurality of users (see column 9 lines 19-35).

Regarding claim 31, de la Huerga in view of Sagar disclose a method wherein medication-taking data is received and compliance data is gathered for a plurality of medications (see column 9 lines 19-35).

Regarding claim 32, de la Huerga in view of Sagar disclose a method wherein accessing the compliance data is carried out with proprietary software for programming a remote terminal, tracking the medication-taking data and compliance data, displaying the medication-taking data and compliance data, and generating custom reports (see column 4 lines 6-20).

**Conclusion**

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael K. Collins whose telephone number is (571) 272-8970. The examiner can normally be reached on 8:30 am - 5:00 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gene O. Crawford can be reached on (571) 272-6911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

M.C.  
8/17/2006

  
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